

Remarks

Amendment to claims

Claim 1 is amended to correct an obvious error.

Claim Rejections 35 U.S.C. § 103

Claims 1-3, 5-6, 9-10, 15 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neff et al. in view of Johnson et al.

Neff et al. concerns the discovery that the *Arabidopsis* *bas1* gene is involved in brassinolide activity. Neff et al. generated approximately 3000 transgenic plants containing T-DNAs with an enhancer element, and identified plants having significantly shorter hypocotyls than the T₀ *phyB-4* mutant parents (see col. 38, lines 10-32). It was determined that in the plants with this desired phenotype, the T-DNA/enhancer element had inserted near and caused overexpression of the *bas1* gene (see col 38, lines 34-48). Recapitulation lines, in which a *bas1* transgene was overexpressed in a *phyB-4* mutant, reproduced the short hypocotyls phenotype (see col. 38, line 53-61).

Several of the passages in Neff et al. that are cited by the Examiner as teaching elements of the rejected claims concern the *bas1* recapitulation lines, and not the T-DNA/enhancer lines, and thus are not relevant to the invention of claim 1 because the *bas1* transgene of the recapitulation lines would not be considered “a random insertion of an insertional mutagen in the genome” as set forth in part (a) of claim 1. In particular the examiner cited col. 5 for teaching inserting a transgene into the genome of a plant and producing seed; col. 13 for teaching the use of a selectable marker; col. 17 for teaching self-crossing transformed plants and growing seed to produce a 2nd generation having the mutant phenotype; and col. 48 for teaching analysis of T2 plants by digital imaging – however, each of these passages concerns *bas1* recapitulation lines.

A key feature of applicants claimed invention that is not taught or suggested by Neff et al. is:

g) analyzing a T2 plant grown in (e) for mutant traits and recording in the database any mutant traits observed in the analyzed T2 plant that **were not present** in its parent T1 plant... (emphasis added).

Applicants' invention provides a means by which loss-of-function mutations, which are typically recessive and therefore do not generally produce phenotypes in T1 transformants, can be generated and identified through analysis of related T2 plants. In contrast, Neff et al. was concerned with T1 progeny that exhibited a different hypocotyl phenotype from

parent plants (see col. 38, lines 13-16). There is no evidence that they were interested in T1 transformants that did not exhibit phenotypes that differed from the parental line. There is no evidence that Neff et al. collected T2 seed from T1 transformants that did not exhibit any phenotypes of interest and analyzed for mutant traits “that were not present in its parent T1 plant” as recited in part (f) of claim 1. Thus, Applicants’ invention provides a distinct advantage over the methods of Neff et al. in that both loss-of-function and gain-of-function mutations can be analyzed.

The Examiner cited US Pat. No. 6,455,758 to Johnson for teaching “databases for use in plant breeding wherein phenotypic traits and genotypes are recorded and linked to each other (col. 4, lines 49-68)”. Column 4, lines 49-68 of Johnson is reproduced here:

- (a) forming a phenotypic trait database in a first plant population of the species by quantitatively assessing the distribution of a numerically representable phenotypic trait in the first plant population;
- (b) forming a first genotypic database in the first plant population by genotyping members of the first plant population for one or more inherited genetic markers;
- (c) evaluating the phenotypic trait database in conjunction with the first genotypic database to define an association between the numerically representable phenotypic trait and the inherited genetic marker(s);
- (d) forming a second genotypic database in a second plant population of the species by genotyping members of the second plant population for the inherited genetic marker; and
- (e) predicting the values of the numerically representable phenotypic trait of all members of the second plant population using the association and the second genotypic database.

It is not apparent to Applicants how this passage teaches that “phenotypic traits are recorded and linked to each other” as alleged by the Examiner.

The Examiner states further that “it is noted that JOHNSON specifically teaches that his databases may be used to link a genetic marker and phenotype in successive generations of plants, including hybrids (col. 6, lines 25-42)” (Office action, ¶¶ bridging pp 4-5). Column 6, lines 25-42 of Johnson is reproduced here:

In a still further aspect, the present invention provides a process for predicting the value of a numerically representable phenotypic trait in a plant of a given species, which process comprises the steps of:

- (a) determining an association between at least one genetic marker and at least

one numerically representable phenotypic trait in a first plant population at a first descendant generation of a first seminal F₁ hybrid plant;

(b) genotyping a second plant from a second descendant generation of the same or a different F₁ hybrid plant, the second generation at or beyond the first; and

(c) predicting in the second plant the value of the numerically representable trait by applying an equation that defines an association between at least one of the genetic markers and the numerically representable phenotypic trait in the first plant population.

However, the above passage relied upon by the Examiner makes no reference databases or linking information. In fact, after performing the tedious task of searching every occurrence of “link” in the Johnson patent, it is evident that the word is never used in the context of linking database information.

The Examiner concludes that “it would have been obvious... to have identified each transformed plant in the method of NEFF and to have linked particular (identified) plants to both genotypic and phenotypic traits seen in subsequent progeny, as taught by JOHNSON, where the motivation would have been to follow and predict distributions of traits in order to breed for desired phenotypes, as taught by JOHNSON” (Office action, p. 5). Applicants disagree with the Examiner’s analysis. Neff concerns genetic modification of plants to produce plants having a desired phenotype, it does not concern breeding for desired phenotypes. Therefore, there is no motivation to combine the teachings of Neff with that of Johnson to “predict distributions of traits in order to breed for desired phenotypes.”

Furthermore, to establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art (MPEP §2143.03; *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). There are several features of claim 1 that are not taught or suggested by either Neff or Johnson. These include:

(in part b) assigning a T1 identification number to each transformed T1 plant

(in part c) assigning a T2 identification number to said [T2] seed, wherein the T2 identification number is linked to the T1 identification number;

(in part f) recording in the database any mutant traits observed in the analyzed T2 plant that were not present in its parent T1 plant; and

(in part f) a record is generated that associates the information of the analyzed T2 plant to any information recorded about its parent T1 plant.

Because the Examiner has not provided reasoning as to how the prior art teaches or suggests these claimed features, *prima facie* obviousness has not been established, and the rejections under 35 U.S.C. §103 should be removed.


The remaining rejections raised against dependent claims 4, 7, 8, 11, and 16-21, all rely on the rejection of claims 1-3, 5-6, 9-10, 15 and 22-25 as being unpatentable over Neff et al., in view of Johnson et al. However, if an independent claim is nonobvious under 35 USC 103, then any claim depending therefrom is nonobvious (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Accordingly, the rejections raised against the dependent claims are not addressed herein. Applicants make no admissions or concessions regarding the Examiner's assertions with respect to what the additional cited references disclose and their relevance to the claimed invention.

Closing remarks

It is believed that all of the rejections are overcome, and that the claims are in condition for allowance. The examiner is encouraged to telephone the undersigned to discuss any further issues that may need resolution prior to allowance.

Respectfully submitted,

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